JUL 2 9 2004

510(k) SUMMARY of SAFETY and EFFECTIVENESS

I. GENERAL INFORMATION

Trade or (Proprietary) Name: Dentium Co., Ltd Implantium

Common or usual name:	Dental Implant
Classification Name:	Endosseous Dental Implant (21 C.F.R. § 872.3640)
Submitter's Name And Address:	Dentium Co., Ltd 27-5 leui-dong, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea
Contact's Name:	Cathryn N. Cambria
Submission Date:	May 17, 2004
Legally Marketed Device To Which Claim Substantial Equivalence:	Astra Tech Implants-Dental System K012965

II. INDICATIONS FOR USE

The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

III. DEVICE DESCRIPTION

The Dentium Co., Ltd Implantium is a device made of pure titanium metal and titanium alloy intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function. It consists of fixture, abutment, mount, mount screw, cover screw, impression coping, analog, impression coping screw and plastic impression cap. Its materials, dimensions, and intended use are similar to devices currently marketed worldwide.

The Dentium Co., Ltd Implantium are available in four diameters (3.4, to 4.8 mm) and four lengths (8, 10, 12 and 14 mm)

The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.

Based on the indication for use, technological characteristics and comparison to the predicate device, the primary function of the Dentium Co., Ltd. Implantium is the same as the Astra Tech Implants-Dental System and raises no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 9 2004

Dentium Company Limited
C/O Ms. Cathryn N. Cambria
Consultant
Arkin Consulting Group, LLC
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K041368
Trade/Device Name: Dentium Company Limited Implantium
Regulation Number: 872.3640
Regulation Name: Endosseous Implant
Regulatory Class: II
Product Code: DZE
Dated: July 20, 2004
Received: July 21, 2004

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

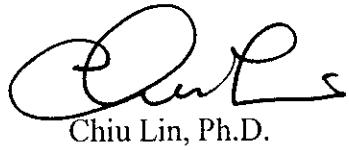
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041368
Device Name: Dentium Co., Ltd
Indications for Use:

The Dentium Co., Ltd Implantium is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.
This may be accomplished by either a two-stage surgical procedure or a single surgical procedure. If a single surgical procedure is used, single or multiple implants may be inserted (type I, II or III bone) provided good initial stability (> 40 Ncm) is achieved. Not intended for immediate loading.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Angela Blackwell for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041368